Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Ex parte H. CRAIG DEES, TIMOTHY SCOTT,
JOHN T. SMOLIK and ERIC A. WACHTER

Appeal No. 2003-1432
Application No. 09/382,622

ON BRIEF

Before ELLIS, SCHEINER and MILLS, Administrative Patent Judges.

ELLIS, Administrative Patent Judge.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1-10, 15, 18-20, 51, 52, 55-57 and 60-67. Claims 11-13, 16, 17, 21-50, 53, 54, 58 and 59 have been canceled. The examiner has indicated that claim 14 is allowable.

As a preliminary matter, we note the appellants' statement on page 11 of the Brief that the claims do not stand or fall together. The appellants state that claims 1, 10 and 51 are independent claims which stand separately. Id. As we understand the

appellants' position, there are three groups of claims; Group 1 consisting of claims 1-9, 15, 19-20, 52, 55-57; Group 2 consisting of claims 10 and 60-63; and Group 3 consisting of claims 51 and 64-67. However, we point out that 37 C.F.R. § 1.192(c)(7)(2003) states that

> For each ground of rejection which appellant contests and which applies to a group of two or more claims, the Board shall select a single claim from the group and shall decide the appeal as to the ground of rejection on the basis of that claim alone unless a statement is included that the claims of the group do not stand or fall together and, in the argument under paragraph (c)(8) of this section, appellant explains why the claims of the group are believed to be separately patentable [emphasis added].

Thus, contrary to the appellants' grouping, we find that with respect to independent claim 1, Group I consists of claims 1-3 and 5-9 (see Rejections I and II, below). In addition, this merits panel selects claim 4 from Rejection III, below, to be separately considered. 37 C.F.R. § 1.192(c)(7)(2003). Thus, Group II consists of claims 4, 15 and 18-20 (see Rejection III). Finally, we find that Group III consists of claims 10 and 60-63; and Group IV consists of claims 51 and 64-67. Accordingly, for purposes of this appeal, we will consider the issues as they apply to claims 1, 4, 10 and 51 which read as follows:

> 1. A radiosensitizer agent for treatment of cancer and tumors, said radiosensitizer agent comprising a halogenated xanthene, said halogenated xanthene interacting with ionizing radiation applied to said cancer or tumor to enhance the therapeutic efficacy of said ionizing radiation.

4. The radiosensitizer agent of Claim 1 wherein said halogenated xanthene includes as a functional derivative at least one targeting moiety selected from the group consisting of deoxyribonucleic acid (DNA), ribonucleic acid (RNA), amino acids, proteins, antibodies, ligands, haptens, carbohydrate receptors or complexing agents, lipid receptors or complexing agents, protein receptors or complexing agents, chelators, encapsulating vehicles[,] short- or long-chain aliphatic or aromatic hydrocarbons, aldehydes, ketones, alcohols, esters, amides, amines, nitriles, and azides.

10. A radiosensitizer agent for treatment of cancer and tumors using ionizing radiation, said radiosensitizer agent comprising a halogenated xanthene wherein said halogenated xanthene is activated using x-rays having an energy greater than 30 keV.

51. A radiosensitizer agent for treatment of cancer and tumors using radiosensitization or ionizing radiation, said radiosensitizer agent comprising a halogenated xanthene wherein said ionizing radiation is approximately greater than or equal to 1 keV and less than or equal to approximately 1000 MeV.

The references relied upon by the examiner are:

Neckers, "Rose Bengal," Journal of Photochemistry and Photobiology, A: Chemistry, Vol. 47, pp. 1-29 (1989).

Norman et al. (Norman), "Iodinated Contrast Agents for Brain Tumor Localization and Radiation Dose Enhancement," Invest. Radiol., Vol. 47, pp. S120-121, (1991).

Serafini et al. (Serafini), "Iodine-123-Rose Bengal: An Improved Hepatobiliary Imaging Agent," Journal of Nuclear Medicine, Vol. 16, pp. 629-632 (1975).

Khaw et al. (Khaw)	5,780,052	July 14, 1998

The claims stand rejected as follows:

I. Claims 1-3 and 5-8 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Serafini.

II. Claims 1-3 and 5-9 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Neckers.

III. Claims 4, 15, 18-20 and 55[1] stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Serafini or Neckers in view of Khaw.

IV. Claims 10, 51, 52, 56-57 and 60-67[2] stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Serafini or Neckers in view of Norman.

We affirm. Our reasons follow.

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[1] We find that claim 55 has not been included in any of the examiner's rejections. We further find that the examiner has not indicated that claim 55 is allowable. Given the subject matter of this claim, it appears that the examiner inadvertently failed to include claim 55 in the § 103 rejection of claims 4, 15 and 18-20. Thus, we have included claim 55 in our deliberations of the issues with respect to these claims.

[2] We point out that claim 60 has not been included in any of the examiner's rejections; nor has the examiner indicated that it is allowable. Given the subject matter of this claim, it appears that the examiner inadvertently omitted this claim from the § 103 rejection of claims 10, 51, 52, 56-57 and 61-67. Thus, we have considered it in our deliberations of the issues with respect to these claims.

Background

The present invention is said to be directed to a method of radiation therapy. Specification, p. 1. According to the specification, normal radiation therapy for cancer patients uses electromagnetic radiation energies of 1 keV (kiloelectron volt) or higher to allow deep penetration into tissue. Id. This high level radiation is said to kill both healthy as well as rapidly growing tumor cells. Id. The appellants' invention is said to overcome many of the problems encountered in the past with radiation treatment because it is directed to a "radiosensitizer agent" comprising a halogenated xanthene which (i) is activated at energy levels greater than or equal to approximately 1 keV and less than or equal to 1,000 MeV (megaelectron volts). Id., pp. 1 and 5. A preferred halogenated xanthene is said to be rose bengal, or its derivative. Id., p. 5.

Discussion

Rejections I and II

As discussed above, the claims of Group I stand or fall with claim 1. Since the dispositive issue in each of the rejections under 35 U.S.C. § 102(b) is the same, and all the claims stand or fall with claim 1, we have considered Rejections I and II jointly.

It is well established that anticipation requires that each and every limitation set forth in a claim be present, either expressly or inherently, in a single prior art reference. In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950 (Fed. Cir. 1999); Celeritas

Techs. Ltd v. Rockwell Int'l Corp., 150 F.3d 1354, 1360, 47 USPQ2d 1516, 1522 (Fed. Cir. 1998); Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d 1452, 1458, 221 USPQ 481, 485 (Fed. Cir. 1984).

The examiner has rejected claims 1-3 and 5-9 as being anticipated by the teachings of Serafini or Neckers. The examiner points out that Serafini discloses a halogenated xanthene, tetrachlorotetraiodofluorescein (a.k.a., rose bengal). The examiner further points out that Serafini discloses the use of an iodinated rose bengal (^{123}I-rose bengal) as a radiopharmaceutical in humans. Serafini, p. 629, col. 2, first complete para. Specifically, Serafini discloses the injection of seven (7) volunteers with 2 mCi of ^{123}I-rose bengal and the recording of its blood clearance using an Anger scintillation camera with a high energy parallel-hole collimator. Id., p. 630, col. 1, last para. Serafini further discloses that their obtention of reduced imaging time and radiation exposure, as well as improved images, demonstrate that their method has improved diagnostic capability for jaundiced patients. Id., the abstract and p. 632.

The examiner points out that Neckers discloses some of the physical and chemical characteristics of rose bengal, a halogenated xanthene. The examiner further points out that Neckers discloses, inter alia, the activation of rose bengal with visible light. Neckers, Tables 2 and 3.

The examiner argues that the halogenated xanthene (rose bengal) taught by Serafini and Neckers is capable of being activated with ionizing radiation and is thus capable of enhancing the therapeutic efficacy of said radiation in the treatment of cancer and tumors. Answer, pp. 4 and 5. The examiner contends that the halogenated xanthene taught by the prior art is identical to the halogenated xanthene set forth in the claims and that the appellants have merely discovered a new property of a known compound. Id.

The appellants' arguments in response thereto can be summarized as neither Serafini, nor Neckers, disclose the use of rose bengal as a radiosensitizer agent which (i) is effective for the treatment of cancer and tumors; and (ii) interacts with ionizing radiation to enhance its therapeutic efficacy. Brief, pp. 19-32. We find the appellants' arguments unpersuasive.

The problem here centers on differing interpretations of representative claim 1 by the examiner and the appellants. The examiner contends that the claim is directed to a halogenated xanthene. The appellants, however, point to the language of the preamble and urge that the claim is directed to a radiosensitizer which is to be used only for treating cancer and tumors. Brief, pp. 12 and 22. Thus, the appellants argue that the preamble confers a limitation on the claim. Id., p. 22.

The determination of whether a preamble limits a claim is made on a case-by-case basis. Catalina Marketing International v. Coolsavings.com Inc., 289 F.3d 801,

808, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). In all cases, the preamble is read in the context of the entire claim. To that end, our appellant reviewing court has held that:

> In general, a preamble limits the invention if it recites essential structure of steps, or if it is "necessary to give life, meaning, and vitality" to the claim Pitney Bowes v. Hewlett-Packard Co., 182 F.3d 1298, 1305, 51 USPQ2d 1161, 1165 (Fed. Cir. 1999);
>
> and
>
> Conversely, a preamble is not limiting "where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention." Rowe v. Dror, 112 F.3d 473, 478, 42 USPQ2d 1550, 1553 (Fed. Cir. 1997).

Catalina Marketing International v. Coolsavings.com Inc., 289 F.3d at 808, 62 USPQ2d at 1785.

Here, we find that representative claim 1 is directed to a compound; i.e., a halogenated xanthene, and not a method. Thus, we agree with the examiner that the preamble merely sets forth an intended use of said compound for treatment of tumors and cancer. We point out that it is immaterial that the applied prior art does not teach the claimed use when said use does not result in a structural difference between the claimed invention and the compound described by Serafini and Neckers. The compound and its properties remain the same. Cf., In re Papesch, 315 F.2d 381, 391, 137 USPQ 43, 51 (CCPA 1963) ("a compound and all of its properties are inseparable; they are one and the same"). To that end, it is well established that "a new intended use for an old product does not make a claim to that old product patentable." In re

Schreiber, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997); In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) (intended use of an old composition does not render composition claim patentable). Thus, we find that since the preamble simply describes an intended use for the compound (halogenated xanthene), representative claim 1 is anticipated by the halogenated xanthene described by Serafini and Neckers.

As to the phrase "said halogenated xanthene interacting with ionizing radiation applied to said cancer or tumor to enhance the therapeutic efficacy of said ionizing radiation," we point out that because the halogenated xanthene taught by Serafini and Neckers is the same as that which is recited in representative claim 1, it (the prior art compound) inherently possesses the claimed characteristics. See, In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)("The discovery of a new property or use of a previously known composition, even when that property and use are unobvious from the prior art, can not impart patentability to claims to the known composition"). In re Woodruff, 919 F.2d 1575, 1578, 16 USPQ 1934, 1936 (Fed. Cir. 1990); Verdegaal Bros., Inc. v. Union Oil Co. of Calif., 814 F.2d at 632-33, 2 USPQ2d at 1054; In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977) (The discovery of a new benefit inherently possessed by the prior art does not render claims drawn to that benefit patentable over said prior art). Thus, the referenced phrase in the

body of representative claim 1 does not provide a patentable limitation to the halogenated xanthene described therein.

In view of the foregoing, we find that Serafini and Neckers disclose every limitation of the claimed invention, either expressly or inherently. In re Robertson, 169 F.3d at 745, 49 USPQ2d at 1950; Celeritas Techs. Ltd v. Rockwell Int'l Corp., 150 F.3d at 1360, 47 USPQ2d at 1522; Verdegaal Bros., Inc. v. Union Oil Co., 814 F.2d at 631, 2 USPQ2d at 1053; Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co., 730 F.2d at 1458, 221 USPQ at 485. Accordingly, we affirm the rejection of representative claim 1 under 35 U.S.C. § 102(b) as being anticipated by Serafini and Neckers. As discussed above, claims 2-3 and 5-9 fall with claim 1.

Rejection III

The examiner argues that claims 4, 15, 18-20 and 55 are unpatentable over the teachings of Serafini or Neckers in view of Khaw. The examiner relies on the teachings of Serafini and Neckers for the reasons set forth on page 6, above. In addition, the examiner relies, inter alia, on the teachings of Khaw with respect to construction of liposomes which are said to enhance the effects of different types of therapy by using known liposome-targeting techniques. Answer, p. 6. Khaw discloses that the liposomes described therein by can contain, inter alia, radiosensitizer and diagnostic agents, such as an imaging agent. Id. The examiner argues that it would have been

obvious to one of ordinary skill in the art to incorporate the halogenated xanthene taught by Serafini or Neckers into the liposomes taught by Khaw in order to target said halogenated xanthene to specific tissues. Id.

In response, the appellants argue that neither Serafini, nor Neckers, discloses or suggests the claimed radiosensitizer agent that acts with ionizing radiation applied to cancer or a tumor to enhance the therapeutic efficacy of the ionizing radiation. Brief, p. 33. The appellants further argue that Khaw does not disclose a halogenated xanthene. Id., p. 34. The appellants still further argue that Khaw discloses methods of making immuno-liposomes which have an immunoreactive moiety such as an antibody on their outside surface, and the use of said immuno-liposomes to deliver their contents to various immunological targets. Id. According to the appellants, the immuno-liposome delivery system taught by Khaw is based on the action of the immunoreactive moiety with specific intracellular antigens; whereas, the present invention only requires simple liposomal formulations for targeting purposes. Id., p. 35. We find these arguments unpersuasive.

It is well established that the examiner has the initial burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness. In re Oetiker, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992); In re Piasecki, 745 F.2d 1468, 1471-72, 223 USPQ 785, 787-88 (Fed. Cir. 1984). It is the examiner's responsibility to show that some objective teaching or suggestion in the applied prior art, or knowledge generally

available in the art, would have led one of ordinary skill in the art to combine the references to arrive at the claimed invention. Pro-Mold & Tool Co. v. Great Lakes Plastics, Inc., 745 F.3d 1568, 1573, 37 USPQ2d 1626, 1629 (Fed. Cir. 1996). This the examiner has done.

Here, we find the teachings of Serafini and Khaw sufficient to sustain the examiner's position. To that end, attention is directed to the teachings of Serafini with respect to the use of an iodinated rose bengal (^{123}I -rose bengal) as a radiopharmaceutical in humans. Serafini, p. 629, col. 2, first complete para. Serafini discloses the administration of 2 mCi of ^{123}I -rose bengal to seven (7) volunteers and that

> sequential scintiphotos of the cardiac pool, liver, biliary system, and intestines were taken at various intervals throughout the study using the Anger scintillation camera with a high-energy parallel-hole collimator. Polaroid scintiphotos with 300,000 counts per view were taken. Utilizing an on-line computer, the data were also recorded and stored for subsequent playback analysis [Serafini, p. 630, col. 1, last para.].

Serafini reports that the data from the studies disclosed therein demonstrate the use of a halogenated xanthene for improved diagnostic studies and the evaluation of hepatobiliary disorders, especially in jaundiced patients. Id., the abstract and p. 630.

Khaw discloses the construction of immuno-liposomes for delivering pharmaceuticals to target cells. Khaw, col. 5, lines 10-15; col. 5, line 50- col. 6, line 19; col. 6, line 51- col. 9, line 11, et seq. Khaw further discloses that said liposomes can be employed for diagnostic purposes. Id., col. 16, lines 29-60. To that end, Khaw reports

that said liposomes can contain a diagnostic agent such as a detectable imaging agent. Id., lines 30-34. Khaw discloses that suitable imaging techniques include gamma cameras and SPECT (single photon emission computed topography) techniques. Id., lines 49-51. Khaw further discloses that alternative imaging techniques using said immuno-liposomes include CAT (computed axial tomography) scans, fluoroscopy and conventional X-ray imaging. Id., lines 52-60.

In view of the foregoing, we find that given the teachings of Khaw with respect to the encapsulation of diagnostic, detectable imaging agents into immuno-liposomes for targeting purposes, it would have been obvious to one of ordinary skill in the art to encapsulate the halogenated xanthene diagnostic agent taught by Serafini into an immuno-liposome in order to target said agent to specific cells such as liver cells.

We point out that to establish a prima facie case of obviousness, the references need not be combined for the purpose of solving the problem as the appellants. See In re Kemps, 97 F.3d 1427, 1430, 40 USPQ2d 1309, 1311 (Fed. Cir. 1996); In re Beattie, 974 F.2d 1309, 1312, 24 USPQ2d 1040, 1042 (Fed. Cir. 1992); In re Dillon, 919 F.2d 688, 693, 16 USPQ2d 1897, 1901 (Fed. Cir. 1990) (en banc), cert. denied, 500 U.S. 904 (1991); In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560 562 (CCPA 1972). Thus, since Khaw suggests encapsulating diagnostic imaging agents within the immuno-liposomes disclosed therein, we find that these teachings would have suggested to one of ordinary skill in the art the encapsulation of any diagnostic imaging

agent, including the halogenated xanthene taught by Serafini.

As to the appellants' argument that its invention only requires simple liposomal formulations for targeting purposes, we point out that representative claim 4 states that the halogenated xanthene includes as a functional derivative at least one targeting moiety selected from the group consisting of . . . encapsulating vehicles . . . . Representative claim 4 is not limited to "simple liposomal formulations for targeting," rather, we find that it encompasses any type of targeting moiety, including those of the type taught by Khaw.

Accordingly, we affirm the rejection of claim under 35 U.S.C. § 103(a) as being unpatentable over Serafini in view Khaw. As discussed above, claims 15 and 18-20 fall together with claim 4.

Rejection IV

As discussed above, the appellants have argued that claims 10 and 51 stand separately. Accordingly, we have considered the issues with respect to these two claims, with the dependent claims standing, or in this case, falling with them.

The examiner argues that claims 10, 51, 52, 56, 57 and 60-67 would have been obvious to one of ordinary skill in the art in view of the teachings of Serafini or Neckers in view of Norman. Answer, pp. 7-8.

Cutting to the chase, we find the teachings of Norman to be, at best, cumulative, and affirm the rejection based on the teachings of Serafini or Neckers primarily for the reasons set forth above with respect to Rejections I and II.

The problem with claims 10 and 51 is that, like claim 1, they are directed to a compound; i.e., to a halogenated xanthene. The preamble of these claims only states an intended use of this compound for the treatment of cancer and tumors. With respect to claim 51, the amount of ionizing radiation of the cancer and tumors does not affect the structure of the claimed compound (halogenated xanthene). As discussed above, "a new intended use for an old product does not make a claim to that old product patentable." In re Schreiber, 128 F.3d at 1477, 44 USPQ2d at 1431; In re Pearson, 494 F.2d at 1403, 181 USPQ at 644.

With respect to claim 10, the activation of halogenated xanthene using X-rays having a specific energy level does not provide a difference between the claimed compound and the halogenated xanthene taught by Serafini and Neckers. That is, the halogenated xanthene taught by the applied prior art inherently possesses the claimed characteristics. As discussed above, the discovery of a new benefit inherently possessed by the prior art does not render claims drawn to that benefit patentable over said prior art. In re Woodruff, 919 F.2d at 1578, 16 USPQ at 1936; Verdegaal Bros., Inc. v. Union Oil Co. of Calif., 814 F.2d at 632-33, 2 USPQ2d at 1054; In re Best, 562 F.2d at 1225, 195 USPQ at 433.

We recognize that the examiner has rejected these claims under 35 U.S.C. § 103(a), and not § 102(b). However, we point out that it is well established that anticipation is the epitome of obviousness. In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 571 (CCPA 1982); In re May, 574 F.2d 1082, 1089,197 USPQ 60,6071 (CCPA 1978); In re Skoner, 517 F.2d 947, 950, 186 USPQ 80, 83 (CCPA 1975); In re Pearson, 494 F.2d at 402, 181 USPQ at 644. Thus, since we find that the teachings of Serafini and Neckers anticipate the inventions described in representative claims 10 and 51, it reasonably follows that said references render the appellants' invention obvious.

Accordingly, the decision of the examiner is affirmed with respect to claims 10 and 51. As discussed above, claims 60-67 fall with claims 10 and 51; and claims 52, 56 and 57 fall with claim 1.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a)

AFFIRMED

JOAN ELLIS
Administrative Patent Judge

TONI R. SCHEINER
Administrative Patent Judge

DEMETRA J. MILLS
Administrative Patent Judge

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